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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,449	03/13/2001	Fu-Tong Liu	051501/027 8726	9750

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/805,449

Applicant(s)

LIU ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-47 is/are pending in the application.
- 4a) Of the above claim(s) 14-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 36-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. The Amendment dated 7/23/04 has been entered into the record.
- B. Claims 1-47 were pending in the application. Claim 13 has been canceled and claims 14-35 have been withdrawn as being drawn to a non-elected invention. Therefore, claims 1-12 and 36-47 are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Claim Rejections - 35 USC § 112, first paragraph – written description***

A. The rejection of claims 1-12 and 36-47 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments and further consideration by the Examiner of the structure of galectin-3. While galectin-3 is 332 residues, various studies, as argued by Applicants, have shown that the ligand binding domain as well as other domains of galectin-3 are known in the art. Therefore, given this guidance and the fact that "fragments" and "subsequences" of galectin-3, as well as antibodies which bind the receptor, comprises a relatively small genus, the Examiner has concluded that galectin-3, its fragments and subsequences as well as its antibodies are adequately described.

B. The rejection of claims 1-12 and 36-47 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments and further consideration by the Examiner of the structure of galectin-3. The rationale used by the Examiner is identical to that of paragraph A in this section.

### ***3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

A. The rejection of claims 5, 6 and 40 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments and further consideration by the Examiner of the structure of galectin-3. The rationale used by the Examiner is identical to that of paragraph A under 35 USC 112, first paragraph, regarding written description.

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B. The rejection of claims 1-12 and 36-47 under 35 USC 112, first paragraph, has been withdrawn in view of the fact that Applicants have provided sufficient guidance and working examples of cells which are encompassed by the claims, such as macrophages, neutrophils and eosinophils as well as monocytes. Furthermore, the types of cells which comprise galectin-3 receptors and which can migrate is sufficiently small.

C. Claims 8-13 and 43-47 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 6-7 of the Office Action mailed 1/21/04. Applicants argue that the claims are not drawn to treating these conditions. While Applicants are correct, it is still unclear how Applicants would be able to maintain a sufficient concentration of galectin-3 at the desired site. It would appear that galectin-3 would diffuse from the intended site. Therefore, any diffusion of galectin-3 would cause the migrating cells to migrate, potentially, away from the site of interest.

#### ***4. Claim Rejections - 35 USC § 112, second paragraph***

A. Claims 1-12 and 36-47 remain rejected under 35 USC 112, second paragraph, for the reasons already of record on page 7 of the Office Action mailed 1/21/04. Applicants have not addressed this argument. Claim 1, for example, is circular. It states a method of modulating migration of a cell by administering a 'modulating amount' of a galectin. Applicants may want to consider such language as, for example, "wherein migration is either increased or decreased (or stimulated or inhibited) depending on the dose of galectin-3," or provide arguments to this rejection.

B. Claims 6 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is confusing since it is not clear how galectin-3 can comprise a "fragment" of itself. The claim could be more clear if it was reworded to recite "comprising a fragment of galectin-3," or "wherein the method uses a fragment of galectin-3." Claim 41 should be amended in a similar fashion.

#### ***5. Conclusion***

A. No claim is allowable.

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***Advisory information***

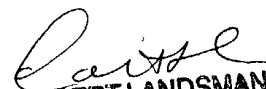
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
August 30, 2004

  
ROBERT LANDSMAN  
PATENT EXAMINER